REMARKS

This is in response to the Office Action that was mailed on July 5, 2005. Claims 1 and 13 are amended to recite a feature of the invention disclosed for instance in lines 18-19 on page 4 of the specification. Claims 1, 6, 12, and 13 are amended to recite a feature of the invention disclosed for instance in Examples 1 and 2 and in the last paragraph on page 9 of the specification. No new matter is introduced by this Amendment. Claims 1, 3, 6, 12 and 13 are pending in the application.

Applicants wish to express their appreciation to Examiner Gitomer for the courtesies extended to Applicants' representative, Richard Gallagher, in a telephonic interview on August 30, 2005. During the course of the interview, Examiner Gitomer indicated that the present Amendment would certainly advance the prosecution of this application. Other input from Examiner Gitomer is reflected in the discussion which follows.

Claims 1 and 13 were rejected under the first paragraph of 35 U.S.C. §112 as failing to comply with the written description requirement. On page 4 of the Office Action, the Examiner implies that this rejection can be overcome by substituting the term "aprotinin" for the phrase "protease inhibitor for inhibition of the degradation of natriuretic peptides" in the claims. Applicants have made that change. Applicants respectfully submit that the claims herein fully satisfy the requirements of the statute.

Claims 1, 3, 6, 12, and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by *Pharmacology & Toxicology* 68:276-281 (Lindberg). The rejection is respectfully traversed.

The Lindberg reference is concerned solely with ***atrial*** natriuretic peptides. Lindberg fails to teach or suggest anything concerning ***brain*** natriuretic peptides. The Lindberg disclosure itself expressly differentiates atrial natriuretic peptides from other types of peptides ("Many peptides ... have a tendency to adhere to different materials, but with respect to this phenomenon the information concerning atrial natriuretic peptide (ANP) is scarce."); page 276, left column.

Inasmuch as Lindberg fails to disclose a process involving ***BNP***, Lindberg manifestly fails to anticipate any of the present claims.

The Lindberg reference teaches processes involving lyophilized α-hANP. Page 276, right column; page 280, Table 1. Inasmuch as Lindberg fails to disclose a process which includes ***obtaining a blood specimen containing brain natriuretic peptide from a subject***, Lindberg manifestly fails to anticipate any of the present claims.

Clearly, the rejection of claims 1, 3, 6, 12, and 13 under 35 U.S.C. §102(b) as being anticipated by Lindberg should be withdrawn.

Claims 1, 3, 6, 12, and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by *Clinical Chemistry* 42:1627-1633 (Clerico). The rejection is respectfully traversed.

The Clerico reference ("Analytical performance and clinical usefulness of a commercially available IRMA kit for measuring atrial natriuretic peptide in patents with heart failure") is concerned solely with ***atrial*** natriuretic peptides. Clerico fails to teach or suggest anything concerning ***brain*** natriuretic peptides. Inasmuch as Clerico fails to disclose a process involving ***BNP***, Clerico manifestly fails to anticipate any of the present claims.

The Clerico reference teaches processes involving aprotinin. Page 1628, right column. Inasmuch as Clerico fails to disclose a process which includes ***obtaining a blood specimen containing brain natriuretic peptide from a subject***, Clerico manifestly fails to anticipate claims 1, 3, and 13.

Clearly, the rejection of claims 1, 3, 6, 12, and 13 under 35 U.S.C. §102(b) as being anticipated by Clerico should be withdrawn.

NONOBVIOUSNESS/REASONS FOR ALLOWANCE. Although no obviousness rejection has been made, Applicants point out that the presently claimed invention is not suggested by the Clerico or Lindberg references. Neither Clerico nor Lindberg teaches or suggests that the degradation of ***brain*** natriuretic peptide in a specimen is inhibited by placing the specimen into a container made of or coated with a material selected from the group consisting of silicone and plastics.

Each of the present claims is expressly directed to methods that are neither disclosed by nor inherent in the disclosure of the references. Claim 6, for instance, is directed to a method for measuring mammalian brain natriuretic peptides in a specimen. Claims 1, 3, 12, and 13 are directed to methods that are expressly focused by their preambles on inhibiting degradation of BNP. This language in the preambles of the claims is "given life and meaning" by the express requirement in the claims, among other things, that *the ratio of* ***BNP immunoreactivity is 50% or more after 24 hours standing at 25°C.***

The Examiner alleges without express basis on page 3 of the Office Action that such stability would be inherent. Regardless of the question of inherency, nothing in the references applied suggests anything at all about ***brain*** natriuretic peptide stability. (The significance of the Examiner's remark that stability would be highly dependent upon temperature and dilution is unclear.) Lindberg relates only to purified ***atrial*** natriuretic peptide. Also, the specimens studied by Lindberg et al. were not bodily samples. The Clerico et al. article indicates that after incubation at 37°C for 30 minutes the specimen without protease inhibitors showed 70.2% degradation. Clerico et al. concluded that aprotinin is necessary for inhibiting the degradation of ***atrial*** natriuretic peptide.

Accordingly, Applicants support the Examiner's decision not to reject any claims herein as being unpatentable over Lindberg or Clerico. Applicants respectfully submit that each of the present method claims is directed to a method of protecting a specific type of natriuretic peptide to a specific quantitative level, and that the methods as claimed are not inherent in the prior art of

record.

Applicants respectfully request the Examiner to withdraw all of the outstanding rejections, and to issue a Notice of Allowance.

If there are any questions concerning the present application, the Examiner is respectfully requested to contact Richard Gallagher (Reg. No. 28,781) at (703) 205-8008.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____
RG Mark J. Nuell, Ph.D.
Registration No.: 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Rd
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant